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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,993	09/28/2005	Jean-Claude Brackman	DECL106.001APC	9456
20995 7590 03/10/2010 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614				
EXAMINER CLARK, SARA E				
ART UNIT 1612		PAPER NUMBER		
NOTIFICATION DATE 03/10/2010		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
efiling@kmob.com
2ros@kmob.com

Office Action Summary

Application No.

10/538,993

Applicant(s)

BRAEKMAN ET AL.

Examiner

SARA E. CLARK

Art Unit

1612

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11-13,15,18 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) 4,6-9,11,13,15,20 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,12,18 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

NON-FINAL REJECTION

Receipt is acknowledged of Applicants' Amendments and Remarks, filed 8/26/2009.

Claims 2, 10, 14, 16, 17, and 19 have been cancelled.

Claims 1, 3, and 5 have been amended and incorporate no new matter.

Claims 4, 6-9, 11, 13, 15, 20, and 22 are withdrawn as drawn to nonelected inventions.

No new claims have been added.

Thus, claims 1, 3, 5, 12, 18, and 21 now represent all claims currently pending and under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statements (IDS) have been submitted.

WITHDRAWN REJECTIONS

Rejections under 35 USC §112

Due to the cancellation of claims 10 and 14, the rejection of claims 10 and 14 under 35 USC 112, second paragraph, has been withdrawn.

Rejections under 35 USC §103

Due to amendments to the claims, the rejection of claims 1, 3, 5, 12, 18, and 21 under 35 USC 103(a) as obvious over Cairns et al. and Ahlem et al. has been withdrawn.

Double Patenting Rejections

Due to the cancellation of claim 14, the rejection of claim 14 for statutory double patenting has been withdrawn.

Due to the abandonment of copending application 10/582,121 on 10/22/2009, the rejection of claims 1, 3, 5, 12, 18, and 21 for obviousness-type double patenting has been withdrawn.

NEW REJECTIONS

Claim Rejections - 35 USC § 112, Second Paragraph

Indefiniteness

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 3, 5, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, page 4 of amended claim 1 recites "wherein X4 and X7 are independently selected from the group consisting of . . . L or D isomers thereof, α or β form thereof, pyranose or furanose form thereof, combination thereof, deoxy derivatives thereof, hydroxyl-protected acetate derivatives thereof, amino derivatives thereof, thio derivatives thereof, di-, tri-, oligo-, and polysaccharide thereof." This recitation is ambiguous, as it is unclear whether "thereof" refers to the immediately preceding listing of defined functional groups from which X4 and X7 may be selected, or to the

compound as a whole. This lack of definiteness obscures the boundaries of the claims such that the public would not be on notice of which particular species are included and excluded from their scope.

Further, page 3 of amended claim 1 recites that "X3 participates together with X3' in an oxo functional group." However, the proviso at the end of amended claim 1 (page 5) recites

provided that when X₆ and X₄ are H, when X₆ participates in a double bond between the carbon atoms in position 5 and 6, when X₅ participates together with X₃' in an oxo functional group, when n is zero and R₁ and R₂ are H, X₇ is not hydroxyl.

That is, the body of claim 1 definitively limits X3 and X3' to an oxo group, while the proviso uses conditional language, implying that X3 and X3' could be functional group(s) other than an oxo group. It is suggested to amend the proviso to clarify that X3 and X3' are fixed (i.e., limited to an oxo group only).

Claim Rejections - 35 USC § 112, First Paragraph

Written Description

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3, 5, 12, 18, and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that Applicant, at the time the application was filed, had possession of the claimed invention. Specifically, the specification fails to define "derivative," in either a limiting or non-limiting way, such that the term as recited in the claims has no clear boundaries.

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter as of the filing date of the application. As recognized in the MPEP:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

In the instant case, the claims are drawn to compounds having a steroid nucleus with fixed groups X1 and X2 (methoxy), R1 and R2 (hydrogen), X3 and X3' (oxo), and variable groups X4, X5, X6, and X7. In particular, the claims define X4 and/or X7 to include a number of functional groups, concluding with "pyranose or furanose form thereof, combination thereof, deoxy derivatives thereof, hydroxyl-protected acetate derivatives thereof, amino derivatives thereof, thio derivatives thereof, di-, tri-, oligo- and polysaccharide thereof." Because "derivative" has no established, commonly understood limit, the possible structural variations are nearly limitless.

The written description requirement of 35 U.S.C. 112 requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, the specification fails to provide adequate written description for "derivatives" and does not reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the full scope of the claimed invention.

CONCLUSION

Claims 1, 3, 5, 12, 18, and 21 are rejected.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to SARA E. CLARK whose telephone number is (571) 270-7672. The examiner can normally be reached on Mon - Thu, 7:30 am - 5:00 pm (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARA E. CLARK/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612